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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,543	10/04/2001	Benjamin Eithan Reubinoff	14418Z	1839

7590 12/16/2004

Scully, Scott, Murphy & presser
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Garden City, NY 11530

EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,543	REUBINOFF ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/808,382.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/3/04, 7/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments filed September 9, 2003 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-64 have been canceled. Claims 65-77 are pending.

Priority is granted.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 65 and 67-77 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious WO 99/11758 11 March 1999 (Carpenter)

Carpenter teaches the transplantation of human ES derived neural progenitor cells isolated from embryonic human forebrain into the left striatum of rat brain (page 20, lines 17-19). A stable graft was produced as demonstrated by M2 immunoreactivity, glial specific marker (page 21, lines 6-9). Carpenter further teaches the treatment of neurodegenerative diseases by administering the human ES derived neural progenitor cells to a patient to replace deficient neurons (page 21, lines 25-27). The transplantation of genetically modified neural progenitor cells into a human patient is taught (page 23, lines 8-10). The progenitor cells since they are of neural origin inherently express specific desired genes in the brain. While applicant's claims state a particular method of producing and culturing neural

progenitor cells for implantation into a host, there is no evidence of record that the neural progenitor cells of the present claims has any distinction from the neural progenitor cells of Carpenter. Thus, Carpenter clearly anticipates the claimed invention, or in the alternative the claims are obvious over Carpenter because there are no distinguishing features of the neural progenitor cells of the present claims and those of Carpenter.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). The PTO does not have the means to determine if the neural progenitor cells of the claims are distinct from those of Carpenter. Applicant needs to provide arguments or evidence that the source of the cells makes a patentable distinction.

Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/11758 11 March 1999 (Carpenter) in view of Martinez-Serrrano et al (1995) J. Neurosci. 15, 5668-5680.

Carpenter teaches the transplantation of human ES derived neural progenitor cells isolated from embryonic human forebrain into the left striatum of rat brain (page 20, lines 17-19). Carpenter does not teach injection into a lateral cerebral ventricle.

Martinez-Serrano teaches the implantation of CNS derived neural progenitor cells transfected with a retrovirus comprising an DNA sequence encoding NGF into the septum of

a rat brain having a complete fimbria-fornix lesion prevent significant loss of cholenergic cell (Martinez-Serrano, page 5676, col. 2, parag. 1, lines 1-7 and figure 7).

Thus, at the time of the instant invention, it would have been obvious to the ordinary artisan to implant human neural progenitor cells of Carpenter into the brain septum of a rat having a complete fimbria-fornix lesion to determine the effect of the graft on the lesion. The claims require nothing more than transplanting neural progenitor cells.

While applicant's claims state a particular method of producing and culturing neural progenitor cells for implantation into a host, there is no evidence of record that the neural progenitor cells of the present claims has any distinction from the neural progenitor cells of Carpenter. Thus, Carpenter clearly anticipates the claimed invention, or in the alternative the claims are obvious over Carpenter because there are no distinguishing features of the neural progenitor cells of the present claims and those of Carpenter.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). The PTO does not have the means to determine if the neural progenitor cells of the claims are distinct from those of Carpenter. Applicant needs to provide arguments or evidence that the source of the cells makes a patentable distinction.

Applicant's arguments are addressed to the extent they are appropriate given the new rejection.

Applicant argues that Martinez-Serrano et al teach immortalized cells derived fro CNS in contrast to the neual progentior differentiated from undifferentiated or pluripotent embryonic stem cells as recited in the present claims. This arguemetn is not persausive because the cells of Carpenter ultimately were derived from human ES cells, as all human cells are so derived. Immortalization is not relevant as Carpenter's cells are not immortalized.

Applicant argues that Fricker, directed to implantation of neural progenitor cells isolated from human embryonic brain tissue, does not teach or motivate to neuroprogentior cells prepared from undifferentiated or pluripotent human ES cells. These arguments are not persausive as there is no distinction between the neural progenitor cells of the claims and those of Fricker. Like Carpenter, the cell of Fricker are not patentably distinct from those of the presently claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no

event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

December 13, 2004